

WHAT IS CLAIMED IS:

1. The use of a rapid-onset selective serotonin reuptake inhibitor, or a pharmaceutically acceptable salt thereof, on an as-needed basis, for the manufacture of a medicament for treatment or management of sexual dysfunction in a mammal in need of treatment.

2. The use of dapoxetine, or a pharmaceutically acceptable salt thereof, on an as-needed basis, for the manufacture of a medicament for treatment or management of sexual dysfunction in a mammal in need of treatment.

3. The use according to claim 2, wherein the mammal is a human male.

4. The use according to claim 3, wherein the sexual dysfunction is selected from the group consisting of premature ejaculation, retarded ejaculation, low sexual desire, sexual aversion, or inhibited orgasm.

5. The use according to claim 4, wherein the sexual dysfunction is premature ejaculation.

6. The use according to claim 5, wherein dapoxetine is administered immediately prior to, to about 12 hours prior to a sexual activity.

7. The use according to claim 5, wherein dapoxetine is administered immediately prior to, to about 8 hours prior to a sexual activity.

8. The use according to claim 5, wherein dapoxetine is administered immediately prior to, to about 4 hours prior to a sexual activity.

9. The use according to claim 5, wherein dapoxetine is administered immediately prior to, to about 3 hours prior to a sexual activity.

10. The use according to claim 5, wherein dapoxetine is administered immediately prior to a sexual activity.

11. The use according to claim 5, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.01 mg to about 200 mg.

12. The use according to claim 5, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.1 mg to about 120 mg.

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-43-

13. The use according to claim 12, wherein dapoxetine or its pharmaceutically acceptable salt is administered orally.

14. The use according to claim 13, wherein dapoxetine or its pharmaceutically acceptable salt is administered in an oral solid dosage form.

5 15. The use of dapoxetine, or a pharmaceutically acceptable salt thereof, on an as-needed basis, for the manufacture of a medicament for treatment or management of premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 8 hours prior to a sexual activity.

10 16. The use according to claim 15 wherein dapoxetine, or a pharmaceutically acceptable salt thereof, is administered immediately prior to, to about 4 hours prior to a sexual activity.

15 17. The use according to claim 15 wherein dapoxetine, or a pharmaceutically acceptable salt thereof, is administered immediately prior to, to about 3 hours prior to a sexual activity.

18. The use according to claim 15 wherein dapoxetine, or a pharmaceutically acceptable salt thereof, is administered immediately prior to a sexual activity.

20 19. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is effective for treating premature ejaculation in a human male, and wherein said packaging material comprises a label which indicates that said pharmaceutical agent can be used for treating premature ejaculation in
25 a human male on an as-needed basis prior to a sexual activity, and wherein said pharmaceutical agent comprises a rapid-onset selective serotonin reuptake inhibitor or a pharmaceutically acceptable salt thereof.

30 20. An article of manufacture comprising packaging material and a pharmaceutical agent contained within said packaging material, wherein said pharmaceutical agent is effective for treating premature ejaculation in a human male, and wherein said packaging material comprises a label which indicates that said pharmaceutical agent can be used for treating premature ejaculation in a human male on an as-needed basis prior to a sexual activity, and wherein said

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pharmaceutical agent comprises dapoxetine or a pharmaceutically acceptable salt thereof.

21. An article of manufacture according to claim 20 wherein the label indicates that dapoxetine is to be administered about immediately prior to, to
5 about 4 hours prior to a sexual activity.

22. An article of manufacture according to claim 20 wherein the label indicates that dapoxetine is to be administered immediately prior to, to about 3 hours prior to a sexual activity.

23. An article of manufacture according to claim 20 wherein the label
10 indicates that dapoxetine is to be administered immediately prior to a sexual activity.

24. A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of a rapid-onset selective
15 serotonin reuptake inhibitor.

25. The method of claim 24, wherein the mammal is a human male.

26. The method according to claim 25 wherein the sexual dysfunction is selected from the group consisting of premature ejaculation, retarded ejaculation, low sexual desire, sexual aversion, or inhibited orgasm.

20 ✓ 27. The method according to claim 26 wherein the sexual dysfunction is premature ejaculation.

28. The method of claim 27, wherein the as-needed basis is about 1 hour to about 8 hours prior to a sexual activity.

29. The method of claim 24 wherein the rapid-onset selective serotonin reuptake inhibitor is dapoxetine, or its pharmaceutically acceptable salt.
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30. The method of claim 29 wherein the therapeutically effective amount of dapoxetine is from about 0.01 mg to about 350 mg.

31. The method of claim 24, wherein said rapid-onset selective serotonin reuptake inhibitor is short acting.

30 32. The method of claim 24 wherein said rapid-onset selective serotonin reuptake inhibitor is delivered in a rapid release formulation.

33. A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to

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the mammal a therapeutically effective amount of a non-rapid-onset selective serotonin reuptake inhibitor delivered in a rapid release formulation.

34. A method of treating or managing sexual dysfunction in a mammal in need of treatment which comprises administering on an as-needed basis to the mammal a therapeutically effective amount of dapoxetine or a pharmaceutically acceptable salt thereof.

35. The method of claim 34, wherein the mammal is a human male.

36. The method of claim 35, wherein the sexual dysfunction is selected from the group consisting of premature ejaculation, retarded ejaculation, low sexual desire, sexual aversion, or inhibited orgasm.

37. The method of claim 36, wherein the sexual dysfunction is premature ejaculation.

38. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 12 hours prior to a sexual activity.

39. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 8 hours prior to a sexual activity.

40. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 4 hours prior to a sexual activity.

41. The method of claim 37, wherein dapoxetine is administered immediately prior to, to about 3 hours prior to a sexual activity.

42. The method of claim 37, wherein dapoxetine is administered immediately prior to a sexual activity.

43. The method of claim 24, further comprising administering a therapeutically effective amount of an additional therapeutic agent for treating or managing a second, different sexual dysfunction.

44. The method of claim 34, further comprising administering a therapeutically effective amount of an additional therapeutic agent for treating or managing a second, different sexual dysfunction.

45. The method of claim 34, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.01 mg to about 200 mg.

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46. The method of claim 34, wherein the therapeutically effective amount of dapoxetine or its pharmaceutically acceptable salt is from about 0.1 mg to about 120 mg.

47. The method of claim 46, wherein dapoxetine or its pharmaceutically acceptable salt is administered orally.

48. The method of claim 47, wherein dapoxetine or its pharmaceutically acceptable salt is administered in an oral solid dosage form.

49. The method of claim 48, wherein dapoxetine or its pharmaceutically acceptable salt is administered as a tablet or a capsule.

50. The method of claim 34 wherein dapoxetine or its pharmaceutically acceptable salt is delivered as a rapid release formulation.

51. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 4 hours prior to a sexual activity.

52. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to, to about 3 hours prior to a sexual activity.

53. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof about 30 minutes to about 3 hours prior to a sexual activity.

54. A method of treating premature ejaculation in a human male which comprises administering orally to the human male about 0.01 mg to about 200 mg of dapoxetine or a pharmaceutically acceptable salt thereof immediately prior to a sexual activity.

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